

Health Intelligence



Partnerships in Health Innovation: Expanding Paradigms of Private Profit and the Public Good

Fall 2016

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Objective of the Session

To bring together life sciences professionals from industry and academia to explore the future of multi-sector innovation partnerships and provide practical advice on harnessing their potential.

Key Questions

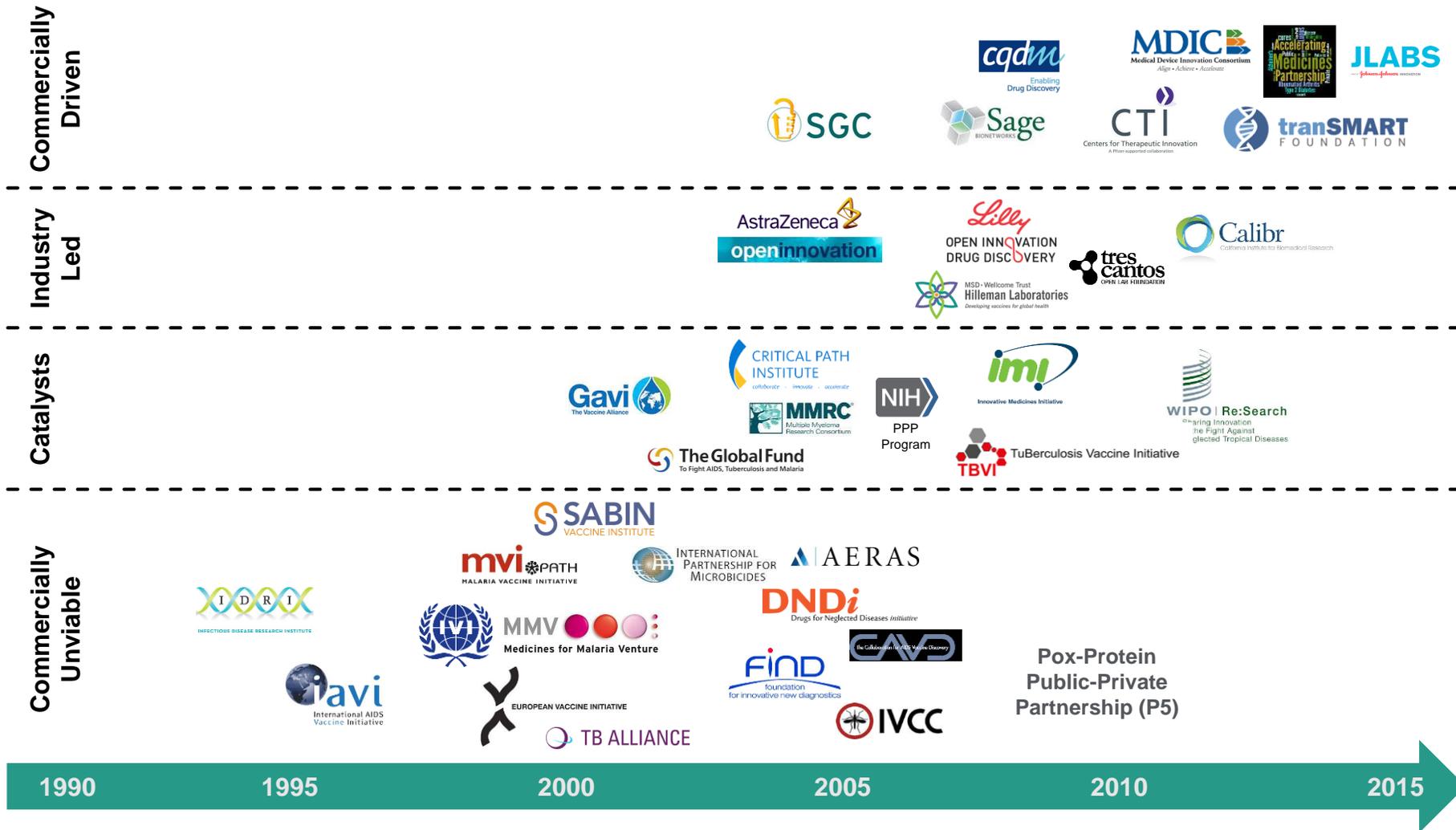
- ◆ What is driving the evolution and diversity of public-private partnerships (P3) in product development?
- ◆ What challenges must be overcome in order to realize the full potential of P3s?
- ◆ What are the success factors and best practices for effective partnerships?

Public Private Partnerships (P3s)—A traditional definition.

*“...use public and philanthropic funds to engage the [life sciences] industry and academic research institutions in undertaking R&D for diseases of the developing world that they would normally be unable or unwilling to pursue independently, without additional incentives.”**

As P3s have flourished globally, so too has creative appetite to experiment with unorthodox models.

There has been a proliferation of innovative partnership models that transcend the traditional definition of P3s.



The growing diversity of potential partnership configurations is guided by different underlying priorities and objectives.



Changes in the R&D landscape are driving experimentation with new models of public-private partnership.

Key Drivers

Industry

Rising costs and risks in product development coupled with **thinning pipelines** and **patent expirations**.

Governments

Unsustainable healthcare costs, increased **global competition** and uncertain global macroeconomic climate.

Academia

Constrained funding for early/preclinical testing, and shifting focus of funders toward **commercialization**.

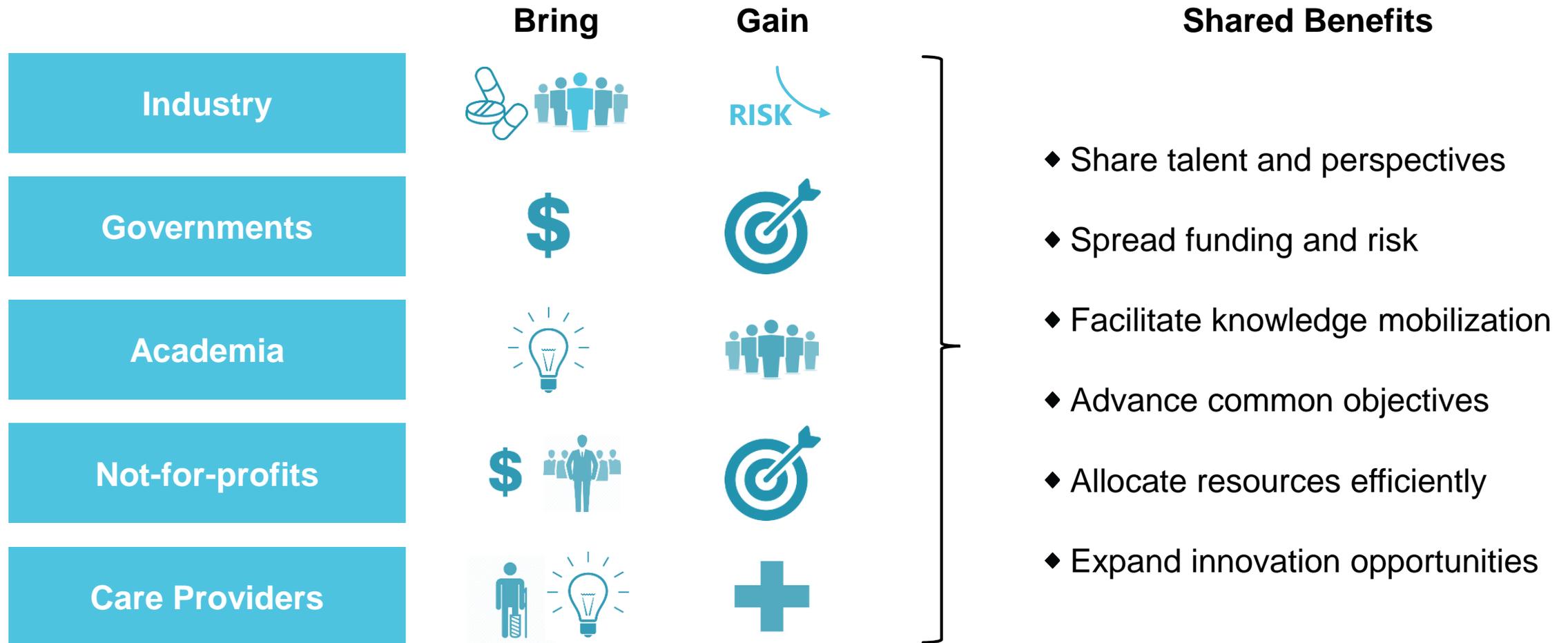
Not-for-profits

Growing demands for **accountability and transparency** by discerning stakeholders/donors.

Care Providers

Emphasis on the **value** interventions contribute to **future health outcomes** requires population-level, real-world data.

Clarifying the expectations of individual partners is critical to realizing benefits that no single partner can achieve on its own.



Realizing the full potential of a P3 is often impeded by the diversity of objectives, priorities and experience among partners.

Power dynamics are challenged by the need to share authority, make joint decisions and hold partners accountable.

Partners speak different languages and with different audiences, leading to potentially damaging misunderstandings.

Creation of IP is both an incentive to innovate and a barrier to collaboration.

While product access is the goal, agreeing to access terms can be complicated by diverse economic expectations.

Technology development efforts are often disconnected from market and business principles.

1

Establish governance mechanisms that enable appropriate participation in decision-making

2

Instill a predictable approach to communication among partners and with stakeholders

3

Develop IP policies that balance the needs of each partner with the objective of the partnership

4

Align partners around the conditions, processes and timelines for making products/technologies available

5

Cultivate an industry mindset by applying business discipline early in technology development

1

Establish governance mechanisms that enable appropriate participation in decision-making.

Transparency

- ◆ Ensure partners understand issues and their role in decision-making

Accountability

- ◆ Clarify roles and responsibilities and establish formal reporting structures

Oversight

- ◆ Ensure that decision-making bodies have authority to act on behalf of the partnership

Focus

- ◆ Establish clear R&D objectives and criteria to guide mission-driven decision-making

1

Case study: Various governance mechanisms are implemented to overcome challenges intrinsic to these often complex relationships.



Each partner is an **equal voting member** on an **Executive Committee** that provides strategic leadership.

A **Scientific Committee** made up of **regional thought leaders** advises the Governing Board.

Diverse Board of Directors representing the **public and private sectors and patient advocacy groups**.

2

Instill a predictable approach to communication among partners and with stakeholders.

Partners

- ◆ Need awareness of activities, challenges and forthcoming decisions/milestones

Scientific Community

- ◆ Desires publication of data and opportunity to discuss scientific results

Funders

- ◆ Expect financial transparency and accountability

Public

- ◆ Requires evidence that activities are mission-driven, ethical and serving the public good

2

Case study: Selected examples of the commitment to communication across a diverse spectrum of PDPs.



Structural Genomics Consortium



Multi-pronged outreach strategy targeting patient groups, schools, radio stations, digital media and policymakers.

Discloses audited financial results, including industry partner contributions, through its Annual Activity Report and website.

Published >100 peer-reviewed articles since 2000 and established 'PLoS Neglected Tropical Diseases' journal.*



*Sabin PDP (originally the Human Hookworm Vaccine Initiative)

3

Develop IP policies that balance the needs of each partner with the objectives of the partnership.

	Target Product	Knowledge/Technology Transfer
Not-for-Profit Partners	Affordable product that will be sold at cost or at a very low margin	Rapid data publication with no restrictions to open access databases
Industry Partners	Marketable product that provides a reasonable return on investment in selected markets	Control access to technology with potential to generate revenue

3 Case study: IP policies are driven by different strategic objectives.



- ◆ Will negotiate an **exclusive global license**
- ◆ Licenses must be **royalty-free** in malaria-endemic countries
- ◆ IP will be **transferable** to manufacturing partners

Support drug access for high-risk populations

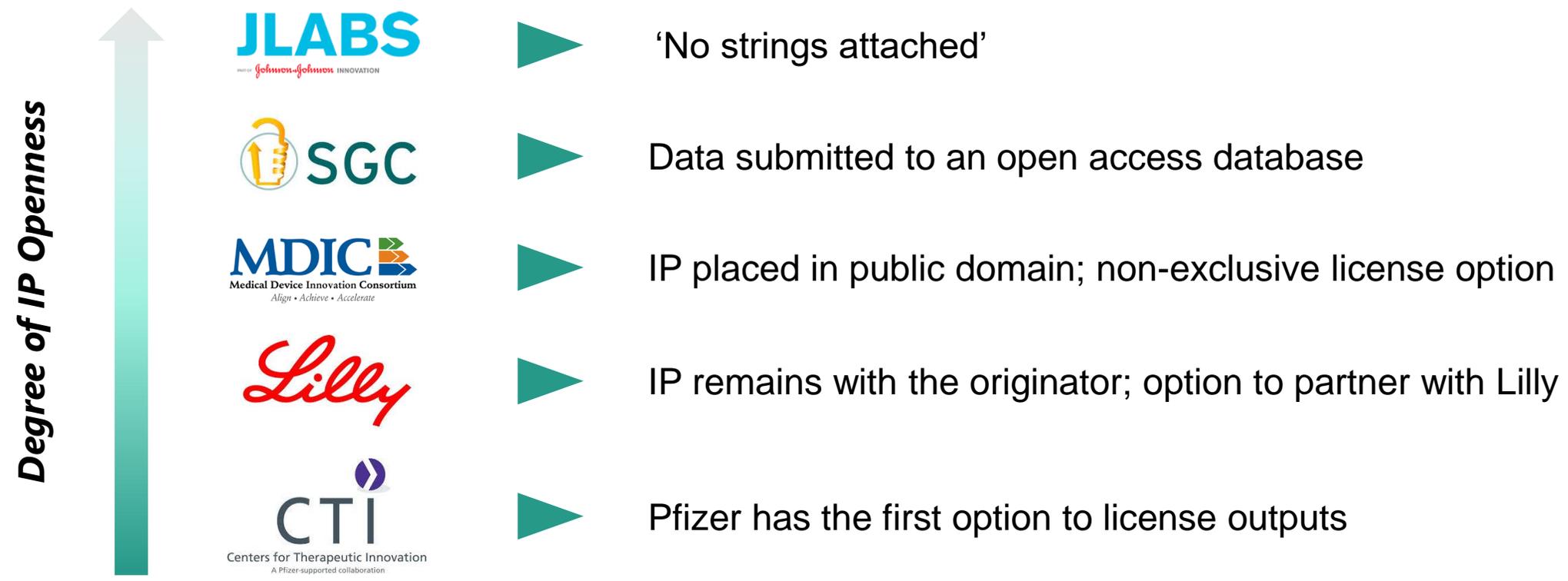


- ◆ Provisions are **adaptable** on a 'case-by-case' basis
- ◆ IMI plays a **neutral, advisory role** during IP negotiations
- ◆ Policy was **co-developed** by and **applies equally** to all partners

Promotes collaboration, innovation and economic growth

3

Case Study: 'Open innovation' partnership models exhibit a diverse array of IP and knowledge/technology access policies.



Flexibility in partnership models has allowed partners to tailor policies to suit individual organizations and achieve the goals of the P3.

4 Align partners around the conditions, processes and timelines for making products/technologies available.

Stakeholder Engagement

- ◆ Understanding **market conditions** and the **needs of end users**

Setting Targets and Thresholds

- ◆ Informing the case for investment by **modelling demand** and **forecasting impact**

Contingency Planning

- ◆ Preparing for **all possible outcomes**

4

Case Study: A clear target product profile and public health impact modelling are key drivers of the P5's access planning efforts.

Pox-Protein Public-Private Partnership (P5)



Lessons Learned

- ◆ Proactive stakeholder communication
- ◆ Plan for success
- ◆ Forecast demand and public health impact

Case Study: P3s in the medical technology space have adopted
4 differing approaches aimed at optimizing access to health innovation.



Supports partners in building capacity for **innovation procurement and/or evaluation studies** relevant for procurement of medical technologies.



Focused on **advancing regulatory science** to understand and evaluate medical technologies and **expedite product development and access**.

5

Cultivate an industry mindset by applying business discipline early in technology development.

Decision-Making

- ◆ Use **stringent thresholds** (e.g. probability of success) to evaluate and prioritize opportunities

Product Development

- ◆ Align all partners around a clear **target product profile** (TPP)

Project Management

- ◆ Set and adhere to an overall **product development plan** and **program strategy**

5

Case study: The Global HIV Vaccine Enterprise, together with Shift Health, held a 2-day Product Development Boot Camp.

Boot Camp Modules:

1. Pipeline and portfolio considerations
2. Target Product Profile (TPP)
3. Moving vaccine concepts from bench-to-clinic
4. Planning for trial success
5. Product development partnerships: best practices



The Boot Camp equipped stakeholders with concepts and tools used by industry to drive product development.

Conclusions

- ◆ P3s have become an increasingly pivotal driver of R&D
- ◆ Partnerships have flourished globally and are becoming increasingly complex
- ◆ Governance, communication and IP/access strategies have diversified—with a common predisposition toward openness and collaboration
- ◆ Experimentation with flexible partnership models to accelerate innovation and advance healthcare solutions will continue

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